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| 10/579,980 | 03/26/2007 | Urban Blomberg | P06,0132 | 3597 |
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| SCHIFF HARDIN, LLP | | | PANI, JOHN | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/579,980 | Applicant(s) BLOMBERG ET AL. |
| | Examiner JOHN PANI | Art Unit 3736 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 May 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 41-79 is/are pending in the application.
 4a) Of the above claim(s) 46, 51, 52 and 54-79 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 41-45 and 47-50 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 19 May 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 3/26/07
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Species A1, B1, and C1 (Claims 41-45, 47-50 and 53 in the reply filed on 5/9/2008 is acknowledged. The traversal is on the ground(s) that Groups I and II/III do no lack corresponding special technical features because Group I and Groups II/III differ in order "to avoid 'claiming the patient.'" This is not found persuasive because while this may have been the intention of the Applicant in drafting the claims, the fact remains that as written, the claims of Group I require that the electrodes are in a position in which they are detecting signals from the diaphragm of the subject while the claims of Groups II and III do not require this feature. Furthermore, as noted by Applicant in page 12 of the remarks, "special technical features' should be features that make a contribution over the prior art", and as described in rejections over prior art below, the claims of Group I do not currently make a contribution over prior art, thus lacking a special technical feature.
2. The traversal is further on the ground(s) that the use of the phrase "automatically electronically" in claim 41 requires the use "some form of computing device" in Group I, and that thus Groups I-III share that feature. This is not persuasive because the language "automatically electronically" could be interpreted to include a thought process of a human mind, while Group II requires a "device" and Group III requires a "computer readable medium". The amended claims 54 and 67 as submitted on 5/9/2008 appear to have overcome the lack of unity of invention between Groups II and III.

3. The traversal of the requirement for election of species is on the ground(s) that "the species identified by the Examiner are, in fact, unquestionably linked to form a general inventive concept, by virtue of depending from a generic independent claim that encompasses all species." This is not persuasive, because the generic independent claim does not include a special technical feature required to fulfill the requirement for unity of invention. Therefore each species previously detailed in the requirement for restriction presents different technical features which lack unity of invention.

4. The requirement for election of species is further traversed on the ground(s) that "the Examiner has deprived the Applicants of the *quid pro quo* of electing a species in response to such a requirement" because the Examiner has not stated that "identical prior art could not then be applied against a divisional application directed to the non-elected species, because of the requirement that the properly-identified species must be patentably distinct." This is not persuasive. The Examiner is unfamiliar with any requirement (within the MPEP) for the Examiner, upon requiring an election of species, to state that identical prior art could not be applied against a divisional application directed to non-elected species. Particularly as one piece of prior art could contain multiple inventions, and could be open to more than one interpretation. It appears that the Applicant may have misconstrued the prohibition by 35 U.S.C. 121 of double patenting rejections between divisional applications filed in response to a restriction requirement which forbids the use of patent issuing on "an application with respect to which a requirement for restriction has been made, or on an application filed as a result

of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent." See MPEP § 804.01 [R-3].

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 41-45, 47-50, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to Claims 41-45, 47-50, and 53

In lines 9-10 of claim 41, the claim recites a step of "estimating...an EMG-signal out of said raw signal." Lines 11-14 recite a step "dependent on...said estimated EMG signal" of "automatically determining an EMG window in a frequency region and filtering said EMG signal out of said raw signal within said window." It is unclear whether "said EMG signal" of line 13 refers to "an EMG-signal" of line 9. Particularly, "said EMG signal" is being filtered out of "said raw signal within said window" in lines 13-14. However, "an EMG-signal" appears to be a signal separate from "said raw signal" in lines 9-10. It is unclear how a "said EMG signal" can be filtered from a raw signal of which it has already been separated. In "said EMG signal" instead refers to a signal separate from "an EMG-signal" of line 9, "said EMG signal" lacks antecedent basis in

the claims. This lack of clarity regarding the metes and bounds of the claim renders the claim and its dependent claims indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 41-45, 47, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,411,843 to Zarychta ("Zarychta").

9. Zarychta teaches:

In reference to Claim 41

A method of determining an EMG-signal out of a raw signal comprising the steps of: obtaining a plurality of signals from a subject via a plurality of electrodes (12a and 12b, or 16a and 16b) configured to interact with the subject to detect signals from the diaphragm of the subject (col. 6 lines 20-40), each electrode having a signal channel associated therewith; combining the respective signals of the signal channels to form a multi-channel raw signal (17); automatically electronically estimating an EKG-signal (76) and an EMG-signal (37-37") out of said raw signal; and dependent on said estimated EKG signal and said estimated EMG signal, automatically electronically determining an EMG window (for example, t_0-t_{17}) in a frequency region and filtering said EMG signal out of said raw signal within said window (col. 8-16).

In reference to Claim 42

The method of claim 41 (see above) comprising filtering said EMG signal from said window (see Figs. 5A-6C).

In reference to Claim 43

The method of claim 42 (see above) comprising automatically electronically dividing said window into at least two sub-windows (see Figs. 6A-6C) with respectively different filtering criteria dependent on said estimated EKG signal and said estimated EMG signal (cols. 11-14).

In reference to Claim 44

The method of claim 41 (see above) comprising automatically electronically determining a width of said window dependent on said estimated EKG signal and said estimated EMG signal (col. 11 lines 50-65).

In reference to Claim 45

The method of claim 41 (see above) wherein said window has a lower frequency, and automatically determining said lower frequency of said window dependent on said estimated EKG signal and said estimated EMG signal (for example, the frequency of R waves is lower than the frequency of window divisions, etc.).

In reference to Claim 47

The method of claim 41 (see above) comprising automatically electronically estimating a noise signal (98) from said raw signal, and automatically determining an upper frequency of said window dependent on said estimated EMG signal and said

estimated noise signal (note in cols. 11-16, that several parameters of the time windows t_0-t_{17} are determined by characteristics of 98).

In reference to Claim 53

The method of claim 41 (see above) comprising automatically electronically identifying a first derivative of a curve representing said estimated EKG signal, and placing a lower frequency of said window dependent on said first derivative (see col. 11 lines 60-67).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarychta in view of US Pat. No. 5,671,752 to Sinderby et al. ("Sinderby").

In reference to Claims 48-50

Zarychta teaches the method of claim 41 and further teaches using the EMG signal to automatically control a ventilator (col. 16 lines 65-67) but does not teach determining a middle frequency of the estimated EMG and using the middle frequency to monitor/measure at least muscle fatigue and muscle activity of the patient, activating a humanly perceptible alarm dependent on deviation of said monitored of measured muscle fatigue from a reference value, or automatically controlling a ventilator

configured to interact with the patient to provide ventilation support to the patient dependent on said monitored or measured muscle fatigue. Sinderby teaches a method in which the center frequency of a diaphragmatic EMG signal is used to measure muscle activity fatigue and to optimize ventilator support (col. 10 lines 1-20). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Zarychta by using the central frequency of the diaphragmatic EMG signal to measure muscle fatigue in order to automatically optimize ventilator support as taught by Sinderby because this substitution would predictably result in controlling a ventilator using a diaphragmatic EMG signal as taught by Zarychta and Sinderby. Additionally, by controlling the ventilator based on the diaphragmatic fatigue, a humanly perceptible signal would be produced in the form of the motion/sound of the ventilator in response to a deviation of the fatigue from a reference value.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 7/12/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736